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Use of Fibrin Sealant for Prosthetic Mesh Fixation in Laparoscopic Extraperitoneal Inguinal Hernia Repair

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Objective

To evaluate the efficacy of mesh fixation with fibrin sealant (FS) in laparoscopic preperitoneal inguinal hernia repair and to compare it with stapled fixation.

Summary Background Data

Laparoscopic hernia repair involves the fixation of the prosthetic mesh in the preperitoneal space with staples to avoid displacement leading to recurrence. The use of staples is associated with a small but significant number of complications, mainly nerve injury and hematomas. FS (Tisseel) is a biodegradable adhesive obtained by a combination of human-derived fibrinogen and thrombin, duplicating the last step of the coagulation cascade. It can be used as an alternative method of fixation.

Methods

A prosthetic mesh was placed laparoscopically into the preperitoneal space in both groins in 25 female pigs and fixed with either FS or staples or left without fixation. The method of fixation was chosen by randomization. The pigs were killed after 12 days to assess early graft incorporation. The following outcome measures were evaluated: macroscopic findings, including graft alignment and motion, tensile strength between the grafts and surrounding tissues, and histologic findings (fibrous reaction and inflammatory response).

Results

The procedures were completed laparoscopically in 49 sites. Eighteen grafts were fixed with FS and 16 with staples; 15 were not fixed. There was no significant difference in graft motion between the FS and stapled groups, but the nonfixed mesh had significantly more graft motion than in either of the fixed groups. There was no significant difference in median tensile strength between the FS and stapled groups. The tensile strength in the nonfixed group was significantly lower than the other two groups. FS triggered a significantly stronger fibrous reaction and inflammatory response than in the stapled and control groups. No infection related to method of fixation was observed in any group.

Conclusion

An adequate mesh fixation in the extraperitoneal inguinal area can be accomplished using FS. This method is mechanically equivalent to the fixation achieved by staples and superior to nonfixed grafts. Biologic soft fixation with FS will prevent early graft migration and will avoid the complications associated with staple use.

Laparoscopic hernia repair is an effective technique, offering more rapid recovery and less pain than with the traditional open approach; recurrence rates are equivalent to those of the traditional open approach.[1–3] The current methods of laparoscopic hernia repair involve the application of a preperitoneal prosthetic mesh over the hernia spaces, creating a tension-free repair.[4,5] The mesh is fixed in place using metal staples to prevent graft displacement, with consequent hernia recurrence.[6]

Laparoscopic herniorrhaphy is not devoid of complications.[7,8] Some of these complications are inherent to the use of the staples and include sensory nerve entrapment with neuralgia,[9,10] bleeding and hematomas in the space of Retzius, and chronic unexplained groin pain (pubalgias) attributed to staples fixed in Cooper's ligament.[7] Recent reports have suggested performing the preperitoneal hernia

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repair without the use of staples,[11,12] relying on the intra-abdominal pressure transmitted through the peritoneal sac to secure the mesh over the defect.[13] Two recent studies comparing stapled with unstapled repair did not demonstrate an increased incidence of recurrence in the unstapled laparoscopic mesh repair group,[14,15] although the follow-up was incomplete and too short to allow meaningful conclusions. The lack of definitive data has resulted in a reluctance among surgeons to leave the prosthetic mesh in place without fixation because of the risk of migration.

The potential complications associated with stapled mesh fixation in laparoscopic inguinal hernia repair led to consideration of an alternative method of fixation using so-called biologic soft fixation with fibrin sealant (FS). FS is a biodegradable adhesive formed by the combination of human-derived fibrinogen and thrombin activated by calcium chloride, leading to the formation of polymerized fibrin chains, effectively duplicating the last step of the coagulation cascade. After tissue application, it is broken down by fibrinolysis and replaced by a fibrotic layer. Antifibrinolytic agents such as aprotinin are included in the preparation to enhance the life span of the sealant and prolong its effectiveness. In addition to its hemostatic action, the fibrinogen component gives the product its tensile strength and adhesive properties, and the thrombin component promotes fibroblast proliferation.[16]

Fibrin sealant has been available commercially for more than 20 years in Europe and is produced by blood banks from autologous fibrinogen in the United States. FS has been studied extensively and has proven to be effective in numerous clinical applications.[17,18] FS was approved for clinical use in the United States in 1998 and is available commercially (Tisseel, Baxter Healthcare Corp, Hyland Immuno Division, Deerfield, IL). It has been used as a powerful hemostatic agent in cardiothoracic and trauma surgery.[19,20] The adhesive properties of FS and its promotion of wound healing have been well documented.[16,21] This product has also been used to reinforce high-risk gastrointestinal anastomoses,[22] to prevent pancreatic fistulas after distal pancreatectomy,[23] and to stop air leaks after thoracic procedures.[24]

An experimental study in the swine model was designed to evaluate the efficacy of mesh fixation with FS in laparoscopic preperitoneal hernia repair and to compare it with stapled fixation.

MATERIALS AND METHODS

The guidelines of the Animal Research Committee were followed for the care and use of the pigs in this study.

Study Design

Twenty-five Yorkshire cross female pigs weighing 45 to 50 kg were used. The presence of the urethral meatus in the lower abdominal midline interferes with trocar insertion, precluding the use of male pigs. In each animal, a 5 × 6-cm patch of polypropylene mesh (Prolene, Ethicon, Somerville, NJ) was placed in each groin laparoscopically using an extraperitoneal approach. Each prosthetic graft was randomly assigned to one of three groups: grafts fixed with FS, grafts fixed using metal staples (Endopath EMS, Ethicon Endosurgery Inc., Cincinnati, OH), and a control group in which grafts were placed without fixation.

The animals were killed on the 12th postoperative day by an intravenous injection of 12 mL of sodium pentabarbital. Through a lower abdominal laparotomy, the surgical sites, including the grafts and wide margins of surrounding tissues, were removed and evaluated. The following parameters were evaluated: macroscopic appearance (graft alignment, presence of intraperitoneal adhesions, tissue incorporation into the grafts, presence of infection), lateral graft motion, tensile strength between the graft and the surrounding tissues, and histologic findings.

Surgical Procedure

All pigs received 1 g cefazolin intramuscularly before surgery and 500 mg orally at 12-hour intervals for 3 days after surgery. After premedication with teletamine hydrochloride 300 mg and xylazine 300 mg, the pigs were placed in the supine position and anesthetized through orotracheal intubation with halothane.

The development of the preperitoneal space for laparoscopic hernia repair has not been successful in the pig model because of the thin nature of the peritoneum.[25] For the purpose of the study, an original technique using finger dissection for creating the preperitoneal space was developed. A 1-cm incision is made in the midline approximately 7 cm above the pubis, much lower than for the regular extraperitoneal technique. With the aid of two S-shaped retractors, the incision is retracted to one side (right) and carried down to the anterior rectus sheath, thus avoiding the linea alba. A 1-cm lateral incision is made on the anterior rectus sheath, exposing the rectus abdominis muscle. The fibers of the rectus muscle are then spread using retractors, allowing the posterior sheath to be visualized. This sheath is left intact throughout the procedure. A plane between the rectus muscle and posterior sheath is created with the index finger, aiming toward the symphysis pubis until the pubic bone is palpated medially and the pulsation of the external iliac vessels is felt laterally. This allows the development of an extraperitoneal retropubic space into which an 11-mm trocar (Ethicon Endosurgery Inc.) is inserted and used for CO_2 insufflation to a pressure of 10 mmHg. Using the gentle blunt finger dissection technique, we were able to maintain an intact peritoneum in all cases. The midline trocar is used for the video laparoscope, and an additional 11-mm trocar is inserted in the right lower quadrant for the laparoscopic instruments. The dissection was carried bilaterally and the anatomical structures defining the potential hernia spaces, including Cooper's ligament, umbilical arteries, inferior

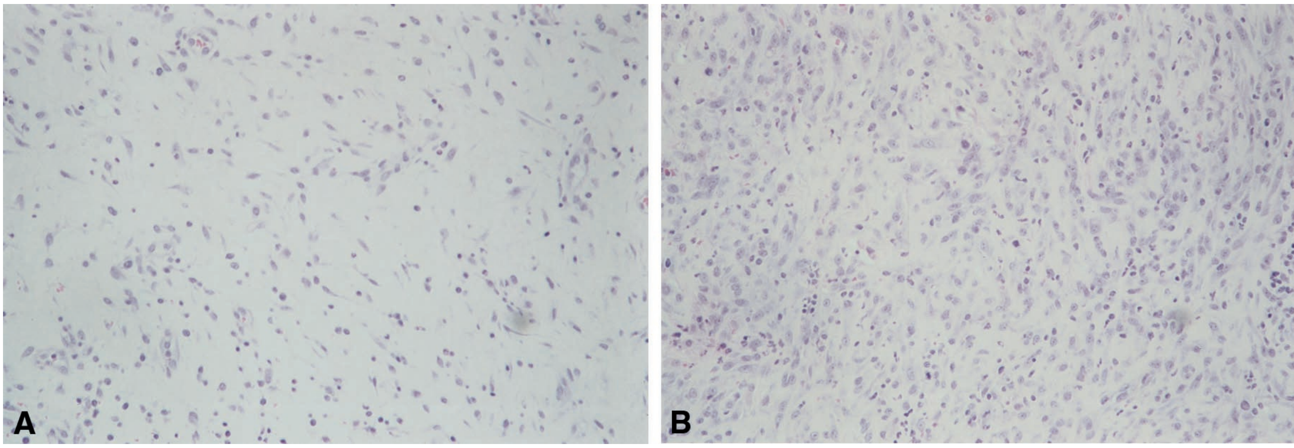

Figure 1. Grades of fibrous reaction. (A) None or few fibroblasts. (B) Predominant and intense fibroblastic reaction).

epigastric arteries, transverse abdominis arch, and iliopubic tract, were identified. On each side, a 5 × 6-cm polypropylene mesh prosthesis was placed lateral to the symphysis pubis and above the iliac vessels, covering the potential hernia spaces.

Stapled grafts were fixed in position with three staples placed in the periphery of the grafts along the superior, medial, and lateral margins, avoiding the iliac vessels and cord structures. For fixation of the mesh grafts with FS, the vials containing the products were first heated at 37° C and agitated in a special warmer (Fibrinotherm, Baxter Healthcare Corp.). After preparation of two syringes containing the fibrinogen mixed with aprotinin and the activated thrombin, a thin uniform layer was applied on the dissected surface of the preperitoneal space using a special laparoscopic applicator (Duplocath, Baxter Healthcare Corp.). The mesh was positioned over the sealant, allowing its penetration through the interstices of the graft. One milliliter of FS was used for each site. Unfixed grafts were held in position during CO_2 desufflation until the expanding peritoneum obliterated the extraperitoneal space.

Graft position was marked by staples placed along the border 1 mm from the grafts to allow precise measurement of postoperative motion. At the conclusion of the procedure, all laparoscopic cannulas were removed, and skin incisions were closed using prolene sutures.

Outcome Measures

At laparotomy, graft incorporation and the presence of infection and intraabdominal adhesions were noted. The following parameters were used to evaluate graft positioning and motion: spatial graft alignment, including mesh folding at the edges; and mesh migration (in millimeters) relative to the marking staples. To evaluate graft incorporation into tissues, measurements of tensile strength between the grafts and the surrounding tissues were performed using an electronic tissue tensometer (Servohydraulic Materials Testing System, MTS Corp., Eden Prairie, MN). A 2-cm strip of the excised graft-tissue specimen was evaluated. Two heavy sutures were placed both in the graft side and in the tissue side of the specimen and then attached to

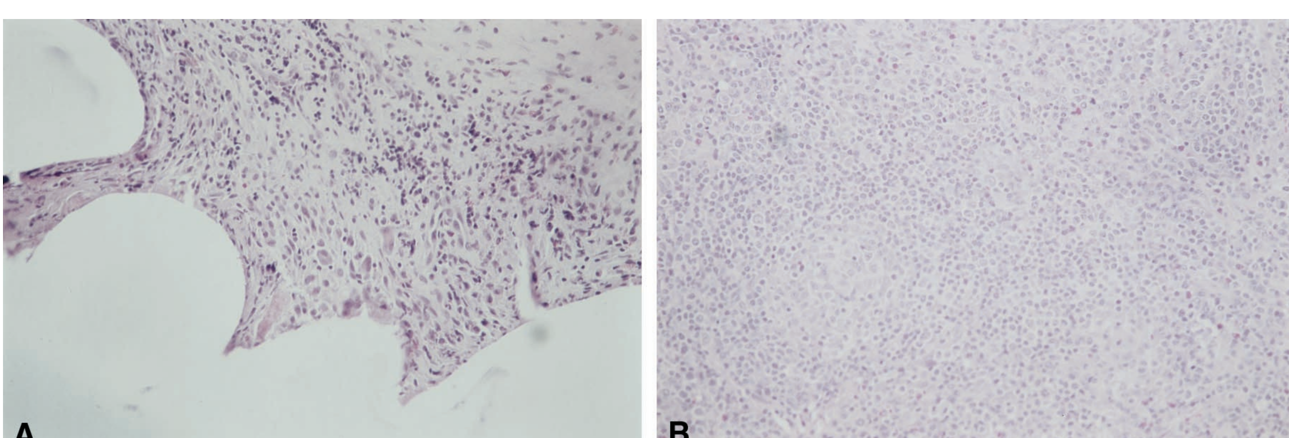

Figure 2. Grades of inflammatory response. (A) Minimal or no inflammatory response. (B) Significant inflammatory reaction (dense lymphoid aggregates).

Table 1. GRAFT MOTION AND TENSILE STRENGTH MEASUREMENTS

	FS (n = 18)	Staples (n = 16)	No Fixation (n = 15)	*P* Value: FS vs. staples	*P* Value: FS vs. no fixation	*P* Value: Staples vs. no fixation
Graft motion (mm)	0 (0–2)	0	5 (0–10)	NS	<.01	<.001
Tensile strength (kg)	0.955 (0.25–3.2)	1.03 (0.09–4.5)	0.46 (0.16–2.64)	NS	<.01	<.01

FS, fibrin sealant.
Results are expressed as median (range).

the corresponding sides of the tensometer. The tensometer was run at a constant speed of 5 inches per minute, and the breaking point of the graft from the tissues was measured in kilograms. Applied uniformly in all three groups, this technique of measuring tensile strength can be used as a standardized assessment of the quality of mesh fixation.

Two 1 × 1-cm specimens were taken for histologic evaluation from each site. One specimen was taken from the edge of the mesh with an adjacent 0.5 cm of surrounding tissue, and the second was taken from the center of the mesh. The specimens were placed in formalin and then embedded in paraffin and stained with hematoxylin and eosin. A total of 92 slides were prepared. Two histologic parameters were evaluated by a blinded pathologist: the amount of fibrous reaction, using a two-point semiquantitative scale (1, mostly native collagen aggregates, no or very few fibroblasts; 2, intense fibroblastic reaction) (Fig. 1), and intensity of the inflammatory response, as determined by the presence of lymphocytes and plasma cells, using a similar scale (1, little or no inflammatory response; 2, significant inflammatory reaction, dense lymphoid aggregates) (Fig. 2).

Statistical Analysis

Data are presented as median and range unless otherwise specified. The differences between the three groups were compared using the Kruskal-Wallis test. Differences between individual groups were compared using the Mann-Whitney test. $P < .05$ was considered significant.

RESULTS

Successful laparoscopic extraperitoneal placement of prosthetic grafts was accomplished in 49 sites. In one instance, bleeding during the dissection did not allow for an accurate placement of the mesh. Eighteen grafts were fixed with FS, 16 were fixed with staples, and 15 were placed without fixation. All grafts were located in the preperitoneal space, and none migrated intraabdominally. Intraperitoneal adhesions were noted in 11% of the sites where FS was used, in 19% where staples were placed, and in 13% of the sites without fixation (P = NS). Infection was noted in one pig on both sides (FS and control). No other site demonstrated evidence of infection.

Graft Motion

The median lateral graft motion in the FS group was 0 mm (range 0 to 2 mm), and there was no significant difference when compared with the stapled group (motion = 0 mm; $P = .96$). These results contrast with those of the nonfixed grafts (median motion 5 mm, range 0 to 10 mm; FS vs. no fixation, $P < .01$; staples vs. no fixation, $P < .001$) (Table 1). On further inspection, a striking feature of the grafts fixed with FS was their smooth, undistorted, and homogenous appearance, with intimate tissue incorporation, whereas grafts fixed by staples were easily differentiated from the underlying tissues. In three cases of stapled meshes, the inferomedial borders devoid of staples were folded.

Tensile Strength

The median tensile strength of the FS-fixed grafts was 0.955 kg (range 0.25 to 3.2). This was not significantly different from the median tensile strength in the stapled grafts (1.03 kg, range 0.09 to 4.5). However, the tensile strength in the nonfixed group (0.46 kg, range 0.16 to 2.64) was significantly lower than in the other two groups (FS vs. no fixation, $P < .01$; staples vs. no fixation, $P < .01$) (see Table 1).

Histologic Findings

Two sites were not included because of infection, and two slides were not evaluated because of technical problems; a total of 92 slides were available for evaluation. Raw data are presented in Figure 3 and Figure 4, and the calculated results are summarized in Table 2. The FS triggered a marked fibroblastic ingrowth into the grafts, with a mean fibrous reaction score of 1.94 ± 0.24 (n = 33). This score was significantly higher than the average scores in the stapled group (n = 31, 1.61 ± 0.49, $P < .001$) and in the nonfixed group (n = 28, 1.75 ± 0.44, $P < .05$). There was

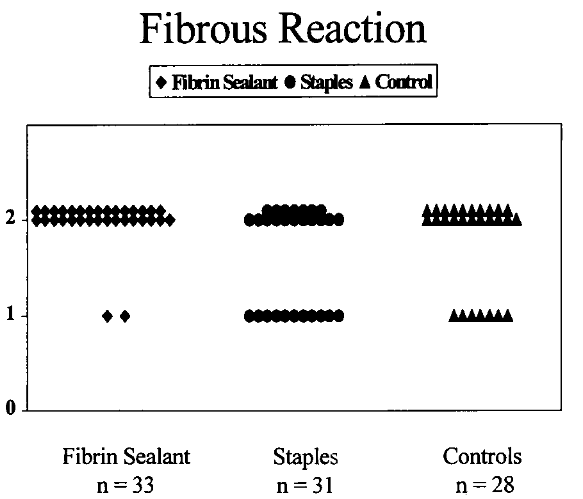

Figure 3. Distribution of the grades of fibrous reaction in the three study groups.

no significant difference in the fibrous reaction between the stapled and nonfixed groups. In both groups, there was comparatively less fibroblastic ingrowth than in the FS group.

The strongest inflammatory response was observed in the FS-fixed grafts (inflammatory score of 2 in all sites). This response was stronger than in grafts fixed by staples (mean 1.67 ± 0.47, $P < .01$) and in grafts placed without fixation (mean 1.85 ± 0.35, $P < .05$). There was no significant difference in the inflammatory response between the stapled and nonfixed groups.

DISCUSSION

This study demonstrates that an effective prosthetic mesh fixation in the extraperitoneal groin area can be achieved by the application of FS under the mesh. We elected to evaluate the quality of mesh fixation with FS 12 days after its application because FS is rapidly degraded by fibrinolysis and replaced by fibrous tissue within 10 to 12 days.[26] Any additional tissue incorporation would be dependent on neocollagen deposition and remodeling.[18] Moreover, fixation is critical during this early period to avoid displacement. After this phase, the secondary healing process is responsible for graft incorporation. The experiment did not involve serial examinations at later dates because fibroblastic ingrowth has already fixed the mesh in position by postoperative day 12, after which further mesh migration or folding is unlikely.

Application of FS under the grafts caused their immediate adherence to the tissues. Mechanically, in terms of graft motion and tensile strength, this fixation was equivalent to that achieved with the use of staples and was superior to the results of the nonstapled mesh. In contrast to grafts fixed by either FS or staples, which showed no lateral motion, nonfixed grafts had an average displacement of 5 mm, with some grafts displaced as far as 10 mm. The uniform adhesion throughout the mesh surface achieved by FS prevented the mesh-folding phenomenon encountered at the unstapled inferomedial border seen in three of the stapled grafts.

In addition to its adhesive property, FS acts as scaffolding for fibroblastic ingrowth that is enhanced by the chemotactic action of its thrombin component.[18] This activity was evident on the histologic evaluation of specimens taken from FS-fixed meshes, where there was a significant fibroblastic growth compared with the other two groups.

The poor tissue incorporation of stapled grafts can be attributed to the relatively early phase of wound healing in which we examined the grafts. Dion et al[27] studied the effects of staple placement on bursting strength in a dog model and demonstrated that stapled fixation is critical to prevent displacement, folding, or invagination of the prosthesis into the hernia defect in the first 2 weeks, before cellular infiltration and collagen deposition anchor the graft in place. The enhanced fibroblastic proliferation and incorporation into the mesh interstices found with FS fixation is probably responsible for its tensile strength, which was comparable to that achieved with staples even in the early phase of wound healing and significantly stronger than in the nonfixed group.

FS incited a significantly stronger inflammatory response than did stapled and nonfixed grafts. The inflammatory response demonstrated in our swine model might be a species-related phenomenon because of the human-derived FS acting as an alloprotein in the animal model.[28] The inflammatory response associated with FS application did not lead to an increased rate of local infection or intraperitoneal adhesions, which were found in 13-16% of the three groups and were related to small peritoneal perforations from dissection of the peritoneal space. The sole infection occurred in one animal on both sides and was probably due to a breakdown in the surgical technique. A significant inflammatory response, however, may be advantageous in

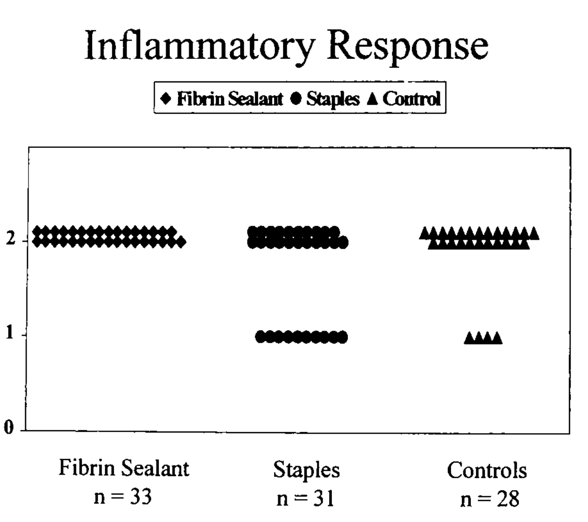

Figure 4. Distribution of the grades of inflammatory response in the three study groups.

Table 2. HISTOLOGIC EVALUATION

	FS (n = 33)	Staples (n = 31)	No Fixation (n = 28)	*P* Value: FS vs. staples	*P* Value: FS vs. no fixation	*P* Value: Staples vs. no fixation
Fibrous reaction*	1.94 ± 0.24	1.61 ± 0.49	1.75 ± 0.44	<.001	<.05	NS
Inflammatory response†	2	1.67 ± 0.47	1.85 ± 0.35	<.01	<.05	NS

FS, fibrin sealant.
Results expressed as the mean score ± SD.
* Grades of fibrous reaction: 1, mostly collagen aggregates, few fibroblasts; 2, mostly fibroblasts, little amount of collagen deposits.
† Grades of inflammatory response: 1, little or no inflammatory response; 2, significant inflammatory reaction (dense lymphoid aggregates).

the setting of prosthetic mesh fixation because it may eventually lead to improved tissue incorporation. In this short-term model, we did not observe other potential problems that might be associated with the increased inflammatory response, such as graft rejection or erosion into adjacent organs.

Avoiding the use of staples in laparoscopic inguinal hernia repair will prevent the inherent complications associated with their use, namely sensory nerve injury and hematomas. Sayad et al,[8] in a collected review of 9,955 laparoscopic hernia repairs, reported a 4.6% incidence of hematomas, 2% neuralgias, and 0.4% chronic pain. A thorough understanding of the preperitoneal inguinal anatomy and precise placement of staples may prevent complications related to injuries to major nerve trunks such as the lateral cutaneous nerve of the thigh and the femoral branch of the genitofemoral nerve, although injuries can occur during the learning curve.[9,29,30] An alternative method of prosthetic mesh fixation, without complications related to staple misplacement, may improve the results of this procedure.

Although minimizing the incidence of complications is one objective during laparoscopic preperitoneal inguinal hernia repair, the rate of recurrence remains the major criterion by which the success of any inguinal hernia repair is measured. In a review of 54 recurrences after 3,229 laparoscopic hernia repairs, Phillips et al[31] found that in 32% of the cases the mesh was not stapled, and in 8% the staples pulled through the tissues. Felix et al,[32] in a large multicenter retrospective review of 10,053 laparoscopic repairs (transabdominal preperitoneal or totally extraperitoneal), found that improper fixation was responsible for failure in 22 of 34 reoperations. Lowham et al,[33] discussing the mechanisms of hernia recurrence after preperitoneal mesh repair, found that the predominant primary factor of recurrence was inadequate dissection of the preperitoneal space. This may leave insufficient room for prosthesis placement, leading to mesh folding or incomplete fixation with displacement of the mesh and potential recurrence. Fiennes and Taylor[34] attributed four of their five recurrences to elevation of the inferomedial edge of the prosthesis caused by desufflation.

To avoid nerve entrapment, the inferior aspect of the mesh located under the iliopubic tract is currently not fixed with staples. This creates a higher risk of folding leading to recurrence initiated by the peritoneum's sliding under the mesh, even when using a large graft.[13] In our study, 3 of 16 grafts fixed with staples were rolled at their inferomedial border.

In contrast to these results, two recent prospective randomized studies comparing stapled versus unstapled laparoscopic inguinal hernia repair, one through a transabdominal preperitoneal approach[15] and the other through a totally extraperitoneal approach,[14] demonstrated no difference between the stapled and the unstapled mesh grafts in terms of hernia recurrence. The follow-up in one study,[15] however, was relatively short (median 16 month, range 1 to 32) and incomplete (12% lost to follow-up and 22% of postoperative follow-ups conducted by phone). The second series[14] was somewhat limited, consisting of 92 patients with a mean follow-up of only 8 months. In another series with a longer follow-up of 30 months, the same author reported a higher recurrence rate of 1.8%.[35]

Our results also indicate that the simple placement of mesh without fixation in the extraperitoneal groin area may not be adequate. The degree of displacement of nonfixed control meshes in our study was significantly greater and the tissue incorporation, as evidenced by tensile strength measurements, was significantly poorer than in meshes fixed either by staples or FS. We nevertheless recognize that data generated from large trials with a longer follow-up might establish nonfixed mesh repairs as an acceptable and safe method in laparoscopic hernia repair.

Fibrin sealant, through its hemostatic effect, has the additional advantage of decreasing the incidence of hematomas created during blunt dissection of the extraperitoneal space, which may cause lifting or displacement of the prosthesis. Wantz,[36] in a report of 386 patients who underwent preperitoneal hernioplasty, noted 16 recurrences, two of which resulted from a hematoma that dislodged the mesh. The use of FS in this setting is supported further by a recent study describing the effectiveness of FS in preventing bleeding after inguinal hernia repair in patients with coagulation problems.[37]

The clinical use of cyanoacrylate synthetic glues as an alternative for polypropylene mesh fixation in laparoscopic hernia repair has been described.[38] However, local toxicity and carcinogenic effect have been reported.[39] FS, however, has the advantage of being biodegradable and has been used successfully for various clinical indications for many years with no significant side effects. A special heat deactivation process and careful screening of donors are essential in the manufacturing process. To date, no transmissible viral diseases secondary to FS use have been reported.[18]

Another current criticism of laparoscopic hernia repair is the cost involved. One could argue that the replacement of staples by fibrin sealant would only add costs to an already expensive procedure. In fact, the use of 1 ml of FS for repair of a unilateral hernia ($100) compares favorably with the cost of a hernia stapler ($170). This does not include the potential cost savings due to the avoidance of staple-related complications and the associated societal economic impact.

In conclusion, based on our strong experimental evidence, we believe that FS could replace staples for mesh fixation in laparoscopic extraperitoneal inguinal hernia repair. The combination of soft fixation obtained with FS and the natural adherence achieved in the extraperitoneal position by intraabdominal pressure transmitted through the peritoneum onto the mesh should guard against graft migration and possible hernia recurrence.

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